

CLAIMS

- 1) A composite containing a drug dispersed in an organic carrier selected from a complexing agent or a cross-linked polymer and mixtures thereof, wherein the drug is massively dispersed (in-bulk) within the composite, and is present in amorphous form in a quantity greater than or equal to 50 % by weight, with respect to the total of drug present in the composite.
- 2) The composite according to claim 1, in which the drug and the carrier are present in weight ratios comprised of between 1:0.5 and 1:20.
- 3) The composite according to claim 2, in which the drug and the carrier are present in weight ratios comprised of between 1:1 and 1:10.
- 4) The composite according to claims 1-3, in which the cross-linked polymer is selected from cross-linked polyvinylpyrrolidone, cross-linked sodium carboxymethylcellulose, cross-linked starch, cross-linked dextran, cross-linked polystyrene, cross-linked β -cyclodextrine.
- 5) The composite according to claims 1-4, in which the complexing agent is selected from alpha-cyclodextrine, beta-cyclodextrine, gamma-cyclodextrine, derivatives thereof, maltodextrine.
- 6) The composite according to claims 1-5, in which said organic carrier has a surface area comprised of between 0.05 m²/g and 20 m²/g.
- 7) The composite according to claims 1-6, in which said drug is a drug sparingly soluble in water.
- 8) The composite according to claim 7, in which said drug is selected from nimesulide, ibuprofen, nifedipine, griseofulvine, piroxicam, progesterone, lorazepam.

- 9) The composite as described in the claims 1-8, for use in therapy.
- 10) A pharmaceutical composition containing the composite described in claims 1-8, optionally associated with pharmaceutically acceptable excipients.
- 11) The pharmaceutical composition according to claim 10, formulated as a granulate, pill, mini-pill, capsule, micro-capsule.
- 12) A process for the preparation of the composite described in claims 1-8, comprising the following steps:
 - a) forming a wet mixture of said drug and said organic carrier;
 - b) irradiating the mixture obtained in a), with microwaves such that the mixture is heated to a temperature higher than the melting temperature of the drug, and such temperature is thus maintained for at least 5 minutes.
- 13) The process according to claim 12, in which said wet mixture is formed by adding water to the carrier-drug composite in a quantity comprised of between 0.1 ml/g and 5 ml/g with respect to the dry mixture of the composite.
- 14) The process according to the claims 12-13, in which the pressure at which the irradiation is carried out is comprised of between 1 and 20 bar.
- 15) The process according to the claims 12-14, in which the irradiation with microwaves is carried out in an power range comprised of between 100 W and 5000 W for an overall time up to 120 minutes.
- 16) A process for the preparation of the composite described in the claims 1-8, comprising the following steps:
 - a) mixing together said drug and said organic carrier;
 - b) placing the mixture obtained in a) in a container constituted of a dielectric material having coupling capacity with the microwaves;
 - c) irradiating with microwaves the container containing said mixture, such that the

mixture is heated to a temperature higher than the melting temperature of the drug, and such temperature is maintained for at least 5 minutes.

17) The process according to claim 16, in which said dielectric material is polytetrafluoroethylene loaded with graphite.

18) The process according to the claims 16-17, in which the irradiation with microwaves is carried out in an power range comprised of between 100 W and 5000 W, for an overall time up to 120 minutes.

19) A composite obtainable through the process described in the claims 12-18.